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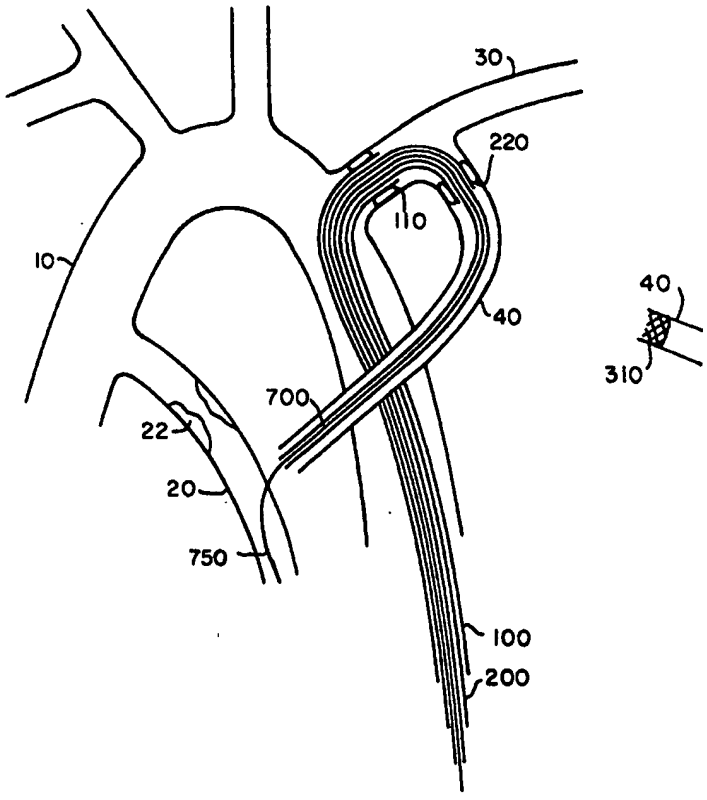
(54) Title: MINIMALLY INVASIVE MEDICAL BYPASS METHODS AND APPARATUS USING PARTIAL RELOCATION OF TUBULAR BODY CONDUIT

(57) Abstract

A tubular body conduit can be partly relocated intralumenally (e.g., to provide a bypass around a narrowing of a tubular body conduit). The tubular body conduit may be plugged intralumenally beyond the part to be relocated. Then the conduit is cut intralumenally. The severed portion of the conduit is relocated intralumenally (e.g., to place the severed end adjacent the side wall of another conduit). The side wall of the other conduit is penetrated intralumenally and the two conduits are connected by a connector that is installed intralumenally.



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MINIMALLY INVASIVE MEDICAL BYPASS METHODS AND APPARATUS USING PARTIAL RELOCATION OF TUBULAR BODY CONDUIT

Background of the Invention

This invention relates to methods and apparatus for treating medical patients who are in need of re-routed body conduits. An example of the use of this invention is in the partial re-routing of a patient's internal mammary artery to provide a bypass around a blockage or constriction in a coronary artery of the patient.

A well-known technique for relieving the adverse effects of a coronary artery blockage or constriction is to sever one of the patient's internal mammary arteries and reconnect the portion of that artery which comes from the aorta to the blocked or constricted coronary artery downstream from the blockage or constriction. The thus re-routed mammary artery supplies the blood flow needed in the downstream portion of the coronary artery.

A disadvantage of known procedures for re-routing an internal mammary artery is that these procedures require either a large opening of the patient's chest cavity or several small openings in that cavity.

In view of the foregoing it is an object of this invention to provide methods and apparatus for reducing the degree of invasiveness of medical treatments involving the partial relocation of a patient's tubular body conduit such as in the relocation of a portion of the patient's internal mammary artery to provide a cardiac bypass connection.

Summary of the Invention

This and other objects of the invention are accomplished in accordance with the principles of the invention by providing methods and apparatus for intralumenally (or at least partly intralumenally) partially relocating a portion of a patient's tubular body conduit. In accordance with the invention, the location at which the patient's tubular body conduit is to be severed is approached intralumenally. A plug may be deposited in the conduit downstream from the point at which the conduit is to be severed. The conduit is then severed from inside its lumen. Any connective tissue between the portion of the conduit that is to be re-routed and surrounding body structures is severed, either by instrumentation which emerges from the severed end of the conduit or which is introduced via a separate opening made into the patient. The portion of the conduit to be re-routed is then intralumenally relocated so that its severed end is adjacent the desired new point of attachment of the severed end. A connector structure attached intralumenally to the severed end of the relocated conduit is then used to form an aperture in the side wall of the other conduit to which the relocated conduit is to be connected. After making this aperture, the connector structure

connects the severed end of the relocated conduit to the aperture in the other conduit.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

Brief Description of the Drawings

FIG. 1 is a simplified sectional view of a portion of a patient's circulatory system.

FIG. 2 is a view similar to a portion of FIG. 1 showing an early stage in an illustrative use of the invention.

FIG. 3 is a view similar to FIG. 2 showing a later stage in the illustrative use of the invention that is shown in part in FIG. 2.

FIG. 4 is a view similar to FIG. 3 showing a still later stage in the illustrative use of the invention that is shown in part in FIG. 3.

FIG. 5 is a view similar to a portion of FIG. 4 showing an alternative to FIG. 4 in accordance with the invention.

FIG. 6 is a view similar to FIG. 4 showing an even later stage in the illustrative use of the invention that is shown in part in FIG. 4.

FIG. 7 is a view similar to FIG. 1 showing a still later stage in the illustrative use of the invention that is shown in part in FIG. 6.

FIG. 8 is a view similar to a portion of FIG. 7 showing an even later stage in the illustrative use of the invention that is shown in part in FIG. 7.

FIG. 9 is a view similar to FIG. 8 showing a still later stage in the illustrative use of the invention that is shown in part in FIG. 8.

FIG. 10 is a view similar to FIG. 9 showing an even later stage in the illustrative use of the invention that is shown in part in FIG. 9.

FIG. 11 is a view similar to FIG. 10 showing a still later stage in the illustrative use of the invention that is shown in part in FIG. 10.

FIG. 12 is a view similar to FIG. 7 showing an alternative to what is shown in FIG. 7 in accordance with the invention.

FIG. 13 is a view similar to FIG. 8 for the alternative illustrated by FIG. 12.

FIG. 14 shows an illustrative embodiment of a portion of the FIG. 2 apparatus in more detail.

FIG. 15 is a view similar to FIG. 14 showing another operating condition of the FIG. 14 apparatus.

Detailed Description of the Preferred Embodiments

Although the invention is equally applicable to other medical treatments in which a portion of a patient's tubular body conduit is relocated, the invention will be fully understood from the following explanation of its application to relocating a portion of a patient's internal mammary artery to provide a bypass around a narrowing in one of the patient's coronary arteries.

FIG. 1 shows a portion of a patient's circulatory system. The depicted portion includes aorta 10, coronary artery 20, brachiocephalic artery 12, right internal mammary artery 14, left common carotid artery 16, left subclavian artery 30, and left internal mammary artery 40. Although a particular coronary artery 20 and a particular internal mammary artery 40 are employed in the illustrative procedure shown and described in detail herein, it will

be understood that the invention is equally applicable to other coronary arteries and/or to the other internal mammary artery (i.e., the right internal mammary artery 14). Thus for convenience and in the interest of generality, artery 40 will usually be referred to simply as an internal mammary artery.

FIG. 1 shows a narrowing 22 in coronary artery 20. To relieve the patient of the problems caused by narrowing 22, internal mammary artery 40 is to be partly re-routed and connected to coronary artery 20 downstream from narrowing 22. In accordance with the present invention, as much as possible of the re-routing and re-connecting of artery 40 is done intralumenally (i.e., through the lumens of the patient's circulatory system). This avoids or reduces the need to make incisions in the patient to gain access to the patient's interior.

As shown in FIG. 2, an illustrative procedure in accordance with this invention begins by inserting a hollow tubular instrument 100 intralumenally into the patient until a distal end of instrument 100 is inside artery 30 upstream from mammary artery 40. For example, the entry point for instrument 100 may be a femoral (leg) artery of the patient, a brachial artery of the patient, or any other suitable entry point which is generally remote from the site at which the bypass is to be performed. The distal portions of instrument 100 and other instruments used with instrument 100 are remotely controlled from proximal portions of those instruments which remain outside the patient's body at all times. Instrument 100 is a catheter-like instrument, and any conventional catheter introducing, guiding, and/or steering technology can be used to introduce instrument 100 into the patient's circulatory

system and cause its distal portion to ultimately pass into and along the patient's aorta to the depicted location in artery 30.

To help temporarily anchor the distal portion of instrument 100 at the depicted location in artery 30 and for other purposes to be described, an annular balloon 110 around the distal portion of instrument 100 may be inflated as shown in FIG. 2 to brace the instrument against the interior wall of artery 30. Balloon 110 may be a perfusion balloon to allow some blood to flow past the balloon, or balloon 110 may be an occlusion balloon to substantially stop the flow of blood through artery 30. In the most preferred embodiment balloon 110 is selectively switchable between perfusion and occlusion so that perfusion can be allowed except for relatively brief periods during which occlusion is required.

After instrument 100 has been positioned as shown in FIG. 2, the distal portion of another elongated instrument 200 is extended distally from the distal end of instrument 100 into mammary artery 40 as is also shown in FIG. 2. Instrument 200 is another catheter-like instrument which may extend coaxially through the interior of instrument 100. Instrument 200 is axially movable relative to instrument 100. Any conventional catheter guiding and/or steering technology may be used to get the distal portion of instrument 200 from the distal end of instrument 100 to the desired location in mammary artery 40. An annular occlusion balloon 210 on the distal portion of instrument 200 may be inflated at any desired time to temporarily stop the flow of blood along artery 40 and to help anchor the distal portion of instrument 200 in that artery.

After instrument 200 has been positioned in artery 40 as described above, the distal portion of a third elongated instrument 300 is extended distally from the distal end of instrument 200 as shown in FIG. 2. The distal end of instrument 300 carries a removable, radially expandable plug 310. For example, plug 310 may be constructed generally as shown and described in Goldsteen et al. U.S. patent application No. 08/839,198, filed April 23, 1997 (Docket No. 293/004), which is hereby incorporated by reference herein. Instrument 300 may also be similar to the plug-deploying instrumentation shown in the immediately above-mentioned Goldsteen et al. reference. Thus instrument 300 is capable of selectively releasing plug 310 so that the plug radially expands to fill and occlude artery 40 downstream from the distal end of the instrumentation as shown in FIG. 3. An illustrative embodiment of plug 310 and plug-deploying apparatus 300 is shown in more detail in FIGS. 14 and 15 and described in a later portion of this specification.

The next step in the illustrative procedure being described is to proximally withdraw plug-deploying instrument 300 and substitute cutting instrument 400. The distal portion of cutting instrument 400 has one or more cutting blades 410 that resiliently extend radially out from the longitudinal axis of instrument 400 when the distal portion of instrument 400 is extended distally beyond the distal end of instrument 200 as shown in FIG. 3. When blades 410 extend radially out, they cut through artery 40. Instrument 400 is then rotated about its longitudinal axis so that blades 410 cut through artery 40 all the way around its circumference. The upstream portion of

artery 40 is thereby severed from the plugged downstream portion of that artery.

The next step in the illustrative procedure being described is to remove cutting instrument 400 and replace it with cutting and cauterizing instrument 500 as shown in FIG. 4. Cutting and cauterizing instrument 500 includes two principal parts. These are rams-horn guide structure 510 and cutting and cauterizing structure 520. Structure 510 is inside structure 520, and these two structures are axially movable relative to one another.

The distal portion of structure 510 includes resilient rams-horn-shaped guide members 512 that are resiliently biased to project radially out from and then backwardly along the longitudinal axis of structure 510 outside artery 40 when the distal portion of structure 510 is extended distally beyond the distal end of instrument 200 as shown in FIG. 4.

The distal portion of structure 520 includes an annular structure 522 that is resiliently biased to radially expand when pushed distally beyond the distal end of instrument 200. Structure 522 can additionally be guided by members 512 to invert and move back along the outside of artery 40 as structure 520 is pushed distally relative to structure 510. For example, structure 522 may be made of a tubular braid of nitinol wires of the general type used for the frameworks of the artificial grafts shown and described in such references as Goldsteen et al. U.S. patent application No. 08/745,618, filed November 7, 1996, and Bachinski et al. U.S. patent application No. 08/839,080, filed April 23, 1997 (Docket No. 293/005), both of which are hereby incorporated by reference herein. (Such a braid may also be used in plug 310.) As described in all of

the above-mentioned references, braids or other similar structures of nitinol can be made extremely flexible and elastic so that structure 522 can have a relatively small diameter inside instrument 200, but when pushed axially beyond the distal end of instrument 200, structure 522 greatly enlarges and can be made to invert and turn back on itself, all as shown in FIG. 4.

The extreme distal tip 524 of structure 522 is made cutting and cauterizing. For example, tip 524 may be heated electrically so that it burns through and cauterizes any tissue that connects mammary artery 40 to surrounding body structures. Structure 522 is pushed distally far enough so that tip 524 moves back up along the outside of artery 40 by a sufficient distance to free the desired length of artery 40 from tissue connections to other body structures. For example, several inches of the length of severed mammary artery 40 may thus be freed from connections to other body structures.

As an alternative to intralumenally cutting and cauterizing tissue connections to severed mammary artery 40, this may be done through a trocar or other similar instrument inserted through the patient's chest wall. This alternative is illustrated by FIG. 5, which shows trocar tube 600 being used to introduce tissue cutting instrument 610 and tissue cauterizing instrument 620 into the patient to cut and cauterize tissue connections to severed mammary artery 40.

The next step in the illustrative procedure being described is to proximally withdraw instrumentation 500 (assuming that instrumentation 500 was used). It may then be desirable to somewhat proximally retract instrument 200 as shown in FIG. 6. To do this, occlusion balloon 210 is deflated, and

after instrument 200 has been suitably retracted, a second occlusion balloon 220 (which is closer than balloon 210 to the distal end of instrument 200) is inflated. During this phase of the procedure balloon 110 preferably occludes artery 30.

The next step is to insert steerable video instrumentation 700 into the patient as shown in FIG. 6. Steerable video instrumentation 700 may be similar to the steerable video instrumentation shown and described in any of Goldsteen et al. U.S. patent application No. 08/745,618, filed November 7, 1996, Bachinski et al. U.S. patent application No. 08/842,391, filed April 23, 1997 (Docket No. 293/006), and Sullivan et al. U.S. patent application No. 08/844,992, filed April 23, 1997 (Docket No. 293/007), all of which are hereby incorporated by reference herein. Thus instrumentation 700 typically includes a light source for illuminating the interior of the patient beyond the distal end of instrumentation 700. Instrumentation 700 also typically includes video components for capturing an image of the interior of the patient beyond the distal end of the instrumentation and for transmitting that image back to a video display which is outside the patient. Instrumentation 700 still further includes steering components that can be controlled from outside the patient to cause the distal portion of the instrumentation to curve and otherwise deflect laterally. And instrumentation 700 may include an axially reciprocable longitudinal member 750 for making an initial penetration of the side wall of coronary artery 20 after other components of the instrumentation have been used to position the distal portion of instrumentation 700 adjacent the coronary artery.

FIG. 7 shows the condition of the patient after the distal portion of instrumentation 700 has been steered to a location adjacent coronary artery 20 downstream from narrowing 22, and also after longitudinal member 750 has been extended from the distal end of instrumentation 700 through the side wall of the coronary artery and into the lumen of that artery. It should be noted that instrumentation 700 takes with it the severed portion of mammary artery 40 as instrumentation 700 is steered to coronary artery 20. Thus the severed end of the upstream portion of mammary artery 40 is also adjacent coronary artery 20 in FIG. 7. Longitudinal member 750 may be a sharply pointed wire that is capable of being pushed through the wall of coronary artery 20 and down into the lumen of the coronary artery. After member 750 has been pushed down into the lumen of coronary artery 20, it helps to keep the severed end of mammary artery 40 adjacent the coronary artery as shown in FIG. 7.

The next step in the illustrative procedure being described is to proximally withdraw instrumentation 700, except for longitudinal member 750. Then connector instrumentation 800 is inserted into the patient through instrument 200 and concentrically around longitudinal member 750 as shown in FIG. 8.

Connector instrumentation 800 includes an inner tubular member 810 concentrically surrounded by an outer tubular member 820. Inside the distal portion of outer tubular member 820 is a connector structure 830. Connector structure 830 includes a serpentine ring 832. Struts 834 extend distally from the distal peaks of the convolutions of ring 832. Struts 834 are bound into a cone shape by annular band 836. An

annular elastic web 838 (e.g., of silicone) is preferably provided between struts 834.

The first step in the use of instrumentation 800 is to push connector structure 830 distally out of the distal end of tubular member 820 as shown in FIG. 9. This may be done by somewhat inflating annular balloon 812 on the distal portion of tubular member 810 and pushing members 810 and 812 distally relative to member 820. When connector structure 830 is beyond the distal end of member 820, ring 820 expands elastically by itself (or is expanded plastically by further inflation of balloon 812 inside ring 832) to firmly annularly engage the inner surface of the distal portion of mammary artery 40.

The next step is to force the cone of struts 834 and the associated web 838 to follow longitudinal member 750 through the side wall of coronary artery 20 as shown in FIG. 10. Any or all of elements 810, 812, and 820 can be pushed distally to push elements 834 and 838 through the coronary artery wall, gradually enlarging the initial aperture previously made by longitudinal member 750 as elements 834 and 838 enter that aperture.

When struts 834 and web 838 are through the side wall of coronary artery 20 to the desired degree, balloon 812 is further inflated inside the cone of struts 834. This causes band 836 to break or otherwise cease to hold struts 834 in their initial cone shape. When released from band 836, struts 834 flare radially out inside coronary artery 20 as they are resiliently biased to do (see FIG. 11). Web 838 continues to provide an annular structure between the struts. In the condition shown in FIG. 11 connector 830 provides a permanent tubular connection between the severed end of

mammary artery 40 and the side wall of coronary artery 20. When all of the instrumentation other than connector 830 is proximally withdrawn from the patient, blood flows through mammary artery 40 and connector 830 into coronary artery 20 downstream from narrowing 22. This provides the desired bypass around narrowing 22 and concludes the illustrative procedure being described.

A possible modification of the above-described procedure is shown beginning with FIG. 12. In this alternative another catheter-type instrument 900 is inserted into the patient's circulatory system so that a distal portion of that instrument extends from aorta 10 into coronary artery 20 through narrowing 22 to the point at which it is desired to connect the severed end of mammary artery 40. Insertion of instrument 900 can be done at any time relative to insertion and use of the other instrumentation described above. Instrument 900 can serve as a source of radiologic fluid in coronary artery 20. Alternatively or additionally, instrument 900 can include radiologic markers in the coronary artery region. These possible radiologic uses of instrument 900 can help the physician make the proper approach to the coronary artery with the severed end of mammary artery 40. As still another possibility, instrument 900 can provide a source of light in coronary artery 20 to help the physician, using the video features of instrumentation 700, make the proper approach with the severed end of mammary artery 40 to the coronary artery.

Instrument 900 may include a longitudinal member 910 which may be somewhat like above-described member 750. At any suitable time after instrument 900

is properly positioned in coronary artery 20, the distal portion of member 910 may be pushed out through the coronary artery wall as shown in FIG. 12. Member 910 may then be used in any of several ways. For example, the distal end of member 910 may provide a light source or another type of highly visible target for facilitating proper relocation of the severed end of mammary artery 40 using the video components of instrument 700. Alternatively or additionally, instrument 700 may include a snare 750a (e.g., at the distal end of longitudinal member 750) for engaging the distal portion of member 910 outside the coronary artery. In that case, after member 910 has been snared, member 750 may be proximally withdrawn while more of member 910 is fed into the patient until member 910 forms one continuous structure at least between arteries 20 and 40, and more preferably into the patient via instrument 900, out the wall of coronary artery 20, into the severed end of mammary artery 40, and out of the patient via instrument 700. Used in this way, member 910 provides a very stable structure for maintaining mammary artery 40 in its desired new location and for guiding connector instrumentation 800 to the location at which connector structure 830 must be installed between the severed end of the mammary artery and the side wall of the coronary artery.

FIG. 13 shows how FIG. 8 is modified for the alternative of FIG. 12, the only difference between FIGS. 8 and 13 being that member 910 replaces member 750. The exact same modification is all that is required to adapt FIGS. 9-11 for this alternative procedure. Providing one continuous structure like member 910 into the patient, through an operative site, and then out of the patient again is similar to what is

done in above-mentioned Goldsteen et al. application No. 08/745,618, and additional details regarding this type of technique and instrumentation suitable for implementing this type of technique will be found in that reference, and also in Bachinski et al. U.S. patent application No. 08/842,391, filed April 23, 1997 (Docket No. 293/006), and Bachinski et al. U.S. patent application No. 08/844,910, filed April 23, 1997 (Docket No. 293/010), all of which are hereby incorporated by reference herein.

Connector structure 830 is only one example of many types of connectors that may be used. For example, in addition to the structure shown in FIGS. 8-11 and 13, connector structure 830 may have prongs that extend radially out from ring 832 and that can enter the tissue of mammary artery 40 to help secure the connector to that artery. Connector structure 830 may also have hooks and/or barbs on the distal ends of struts 834 to help the struts better and more securely engage coronary artery 20 when struts 834 are deployed as shown in FIG. 11. Examples of suitable materials for connector structure 830 are nitinol or stainless steel for all components other than web 838, and silicone for web 838. Additional information regarding possible connector structures and instrumentation for delivering and deploying such structures will be found in above-mentioned Goldsteen et al. application No. 08/745,618, and also in Sullivan et al. U.S. patent application No. 08/844,992, filed April 23, 1997 (Docket No. 293/007), and Bachinski et al. U.S. patent application No. 08/839,199, filed April 23, 1997 (Docket No. 293/008), all of which are hereby incorporated by reference herein.

FIGS. 14 and 15 show an illustrative embodiment of elements 300 and 310 in more detail. In this embodiment plug 310 has the shape of a tube with a closed end (toward the right in FIGS. 14 and 15). Plug 310 is made from an elastic mesh framework 320 covered with an elastic covering 330 which substantially fills the apertures in the mesh. For example, framework 320 may be a braid of nitinol wires, and covering 330 may be a web of silicone. Plug 310 is made so that its substantially relaxed state is as shown in FIG. 15. In this substantially relaxed condition plug 310 has a relatively large diameter (the vertical dimension as viewed in FIG. 15) and a relatively short length (the horizontal dimension as viewed in FIG. 15). However, plug 310 can be elastically deformed to the size and shape shown in FIG. 14 by stretching it axially over the outside of tubular member 300. When thus stretched, the length of the tube increases substantially, but its diameter decreases. In addition, part of the material in its closed end is deformed into more tubular length. After stretching over tube 300, plug 310 is releasably held in that condition by a loop of wire 340 which passes out through aperture 350 in the side wall of tube 300 and through a portion of the side wall of the tubular part of the plug as shown in FIG. 14.

In use, plug 310 is inserted into the patient (FIG. 2) in the condition shown in FIG. 14. When the plug is properly positioned in the patient and it is desired to release the plug, the tension on wire loop 340 is relaxed. This allows plug 310 to begin to return to a shape more like its relaxed shape. In particular, plug 310 begins to axially shorten and to increase in diameter. When it is desired to completely

release plug 310 from the apparatus, one tail of wire loop 340 is released and the other tail of the loop is pulled proximally out of the patient. Eventually the released tail is pulled completely out of plug 310 as shown in FIG. 15 and the plug is thereby completely released from the apparatus.

As has been said, although the shape of plug 310 may be somewhat different from the plug shapes shown in above-mentioned Goldsteen et al. application No. 08/839,198 (Docket No. 293/004), plug 310 may in other respects be constructed as shown and described in that reference.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the depicted connector structure 830 is only one example of many connector structures that can be used, other examples being shown and described in several of the references that are mentioned above. Similarly, the particular internal mammary bypass procedure shown and described herein is only one example of medical treatments to which the invention or various aspects of the invention can be applied. For example, the invention is equally applicable to relocating and reconnecting other portions of a patient's circulatory system tubing or other non-circulatory system tubing of a patient. Radiologic markers can be provided at any desired locations on any of the instrumentation of the invention to help the physician radiologically monitor instrumentation positions within the patient. Alternatively or in addition, any of the instrumentation of the invention can be used to

introduce radiologic fluids into the patient to facilitate radiologic monitoring of the procedure.

The Invention Claimed Is

1. A method for relocating a patient's tubular body conduit comprising:

inserting instrumentation into and axially along the conduit;

using the instrumentation to make an annular cut in the conduit;

using the instrumentation to shift the cut end of the conduit to a new location in the patient's body; and

connecting the cut end of the conduit to the patient's body at the new location.

2. The method defined in claim 1 wherein the new location is adjacent another tubular body conduit, and wherein the connecting comprises:

making a tubular connection between the cut end and the other conduit.

3. The method defined in claim 2 wherein the new location is adjacent a side wall of the other conduit and wherein the making comprises:

forming an aperture in the side wall; and

attaching the cut end to the other conduit via the aperture.

4. The method defined in claim 1 wherein the connecting comprises:

using the instrumentation to deliver a connector to the cut end.

5. The method defined in claim 4 wherein the connecting further comprises:

using the instrumentation to install the connector at the cut end.

6. The method defined in claim 3 wherein the attaching comprises:

using the instrumentation to deliver a connector to the cut end.

7. The method defined in claim 6 wherein the attaching further comprises:

using the instrumentation to install the connector between the cut end and the other conduit via the aperture.

8. The method defined in claim 1 further comprising:

using the instrumentation to install a plug in the conduit at a location spaced from the location at which the annular cut will be made in the conduit.

9. The method defined in claim 1 further comprising:

cutting tissue outside the conduit that connects the conduit to other body structure of the patient.

10. The method defined in claim 9 further comprising:

cauterizing tissue cut in the cutting.

11. The method defined in claim 1 further comprising:

extending a portion of the instrument from the cut end and back along the outside of the conduit to cut tissue outside the conduit that connects the conduit to other body structure of the patient.

12. The method defined in claim 11 further comprising:

cauterizing the tissue cut in the extending.

13. The method defined in claim 1 wherein the conduit is an internal mammary artery of the patient.

14. The method defined in claim 2 wherein the conduit is an internal mammary artery of the patient and wherein the other conduit is a coronary artery of the patient.

15. Apparatus for installing a plug in a lumen of a body conduit comprising:

a longitudinal structure configured for insertion into and along the lumen, the longitudinal structure being adapted to releasably carry a plug structure and to releasably retain the plug structure in a configuration small enough to pass along the lumen with the longitudinal structure, and the longitudinal structure including a plug releasing substructure configured to selectively release the plug structure from the longitudinal structure so that the plug structure can enlarge to plug the lumen.

16. The apparatus defined in claim 15 wherein the plug structure comprises:

an elastic framework; and

an elastic covering over the framework.

17. The apparatus defined in claim 16 wherein the framework is resiliently biased to enlarge to a size which will plug the conduit when the plug structure is released from the longitudinal structure.

18. The apparatus defined in claim 17 wherein the framework defines a tube having a closed end.

19. The apparatus defined in claim 18 wherein the tube is elastically deformable to a greater length and smaller diameter than its relaxed length and diameter.

20. The apparatus defined in claim 19 wherein the longitudinal structure deforms the tube to the greater length and smaller diameter, with the length of the tube being parallel to the longitudinal axis of the longitudinal structure.

21. The apparatus defined in claim 20 wherein the plug releasing substructure is configured to release the tube from the longitudinal structure so that the tube can return to its relaxed length and diameter with the longitudinal axis of the tube parallel to the longitudinal axis of the lumen.

22. The apparatus defined in claim 16 wherein the framework comprises nitinol.

23. The apparatus defined in claim 16 wherein the covering comprises silicon.

24. Apparatus for relocating a patient's tubular body conduit comprising:

a longitudinal structure configured for insertion into and along the lumen of the conduit, the longitudinal structure including:

a first substructure configured to make an annular cut in the conduit;

a second substructure configured to shift the cut end of the conduit to a new location in the patient's body; and

a third substructure configured to connect the cut end of the conduit to the patient's body at the new location.

25. The apparatus defined in claim 24 wherein the longitudinal structure further includes:

a fourth substructure configured to plug the conduit.

26. The apparatus defined in claim 25 wherein the fourth substructure comprises:

a plug-installing structure configured to install a plug in the lumen of the conduit.

27. The apparatus defined in claim 24 wherein the first substructure comprises:

a tissue cutter selectively extendable radially out from the longitudinal axis of the longitudinal structure.

28. The apparatus defined in claim 27 wherein the first substructure further comprises:

a support structure for the tissue cutter, the support structure being rotatable about the longitudinal axis of the longitudinal structure in order to rotate the tissue cutter about the longitudinal axis and produce the annular cut in the conduit.

29. The apparatus defined in claim 24 wherein the third substructure is configured to make a tubular connection between the cut end of the conduit and another tubular body conduit at the new location.

30. The apparatus defined in claim 29 wherein the third substructure comprises:

a tubular connector configured to annularly engage the cut end of the conduit and a side wall of the other conduit via an aperture in the side wall at the new location.

31. The apparatus defined in claim 29 wherein the third substructure comprises:

a tissue penetrating structure configured to penetrate a side wall of the other conduit at the new location.

32. The apparatus defined in claim 31 wherein the third substructure further comprises:

a tubular connector disposed around the tissue penetrating structure and configured to partly follow the tissue penetrating structure through the side wall of the other conduit, thereby producing an enlarged aperture through the side wall.

33. The apparatus defined in claim 32 wherein the third substructure further comprises:

a connector deploying structure configured to cause an axial portion of the connector to annularly engage the cut end of the conduit.

34. The apparatus defined in claim 32 wherein the third substructure further comprises:

a connector deploying structure configured to cause an axial portion of the connector to annularly engage the side wall of the other conduit inside the enlarged aperture through the side wall.

35. The apparatus defined in claim 29 further comprising:

a tissue penetrating structure extending along the lumen of the other conduit and partly out through the side wall of the other conduit at the new location.

36. The apparatus defined in claim 35 wherein the third substructure further comprises:

a structure configured to selectively couple with the part of the tissue penetrating structure which extends out through the side wall of the other conduit at the new location to produce a linking structure between the cut end and the other conduit.

37. The apparatus defined in claim 36 wherein the third substructure further comprises:

a tubular connector disposed around the linking structure and configured to partly follow the linking structure through the side wall of the other

conduit, thereby producing an enlarged aperture through the side wall.

38. The apparatus defined in claim 37 wherein the third substructure further comprises:

a connector deploying structure configured to cause an axial portion of the connector to annularly engage the cut end of the conduit.

39. The apparatus defined in claim 37 wherein the third substructure further comprises:

a connector deploying structure configured to cause an axial portion of the connector to annularly engage the side wall of the other conduit inside the enlarged aperture through the side wall.

40. The apparatus defined in claim 24 wherein the longitudinal structure further includes:

a fourth substructure configured to selectively emerge from the cut end of the conduit and move back along the outside of the conduit to cut tissue connecting the conduit to other body structure of the patient.

41. The apparatus defined in claim 40 wherein the fourth substructure is additionally configured to cauterize cut connecting tissue.

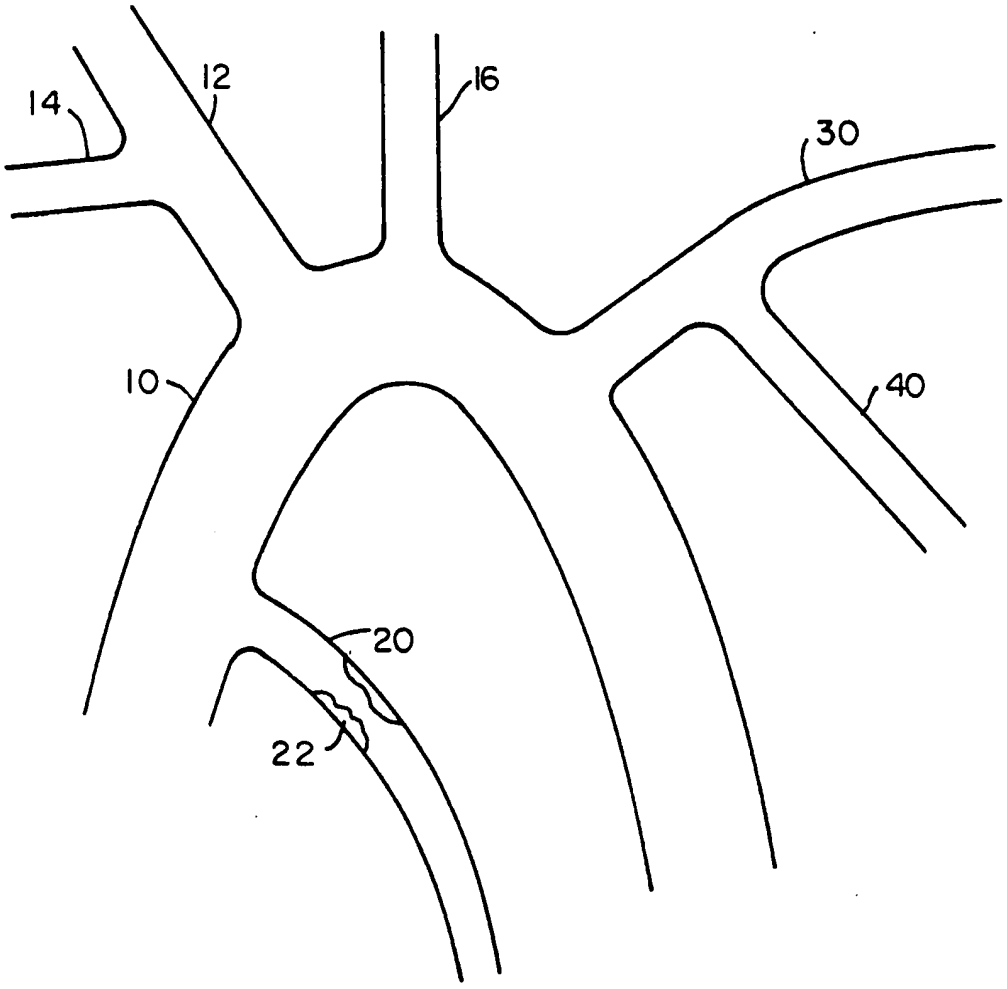


FIG. 1

FIG. 2

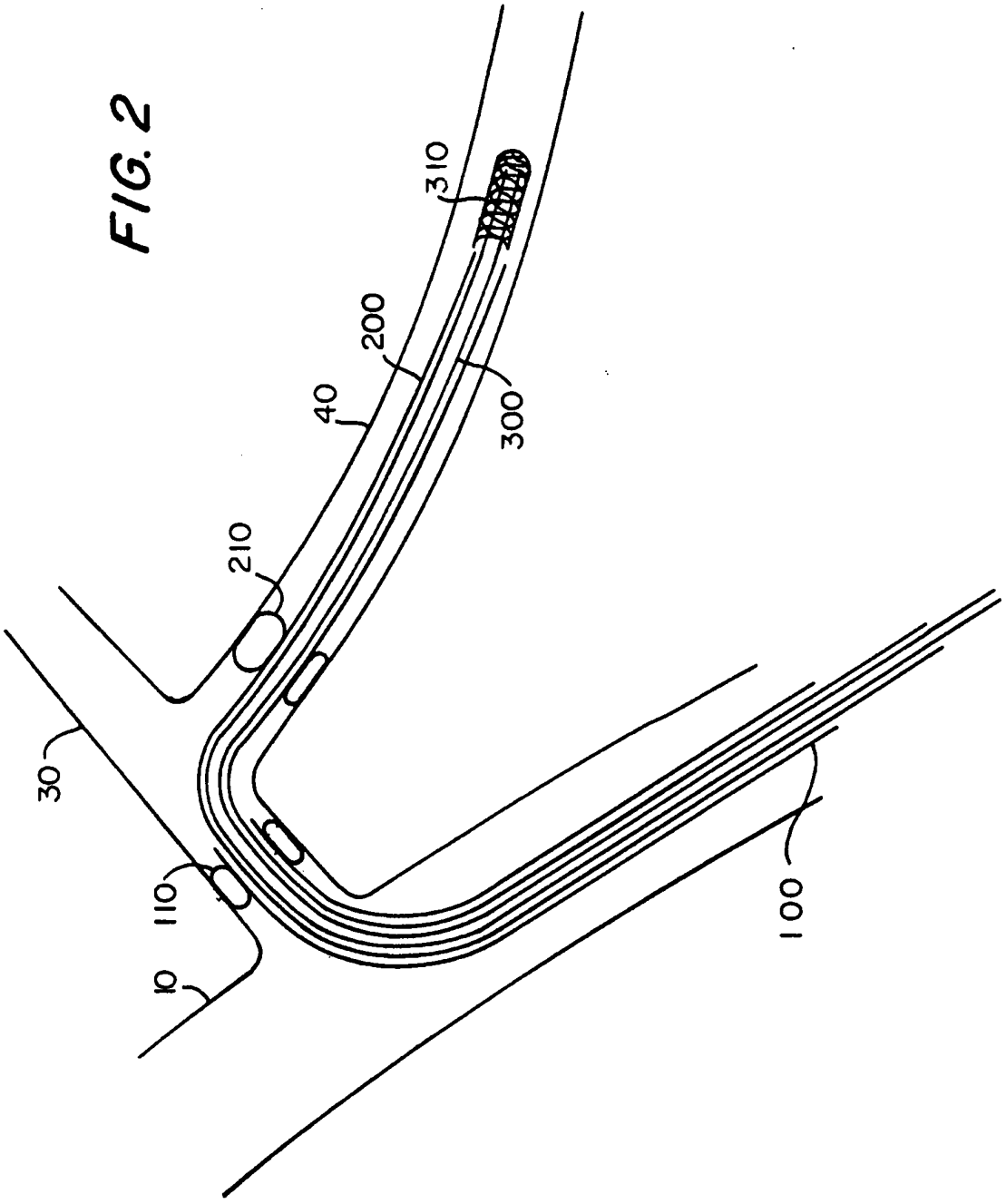


FIG. 3

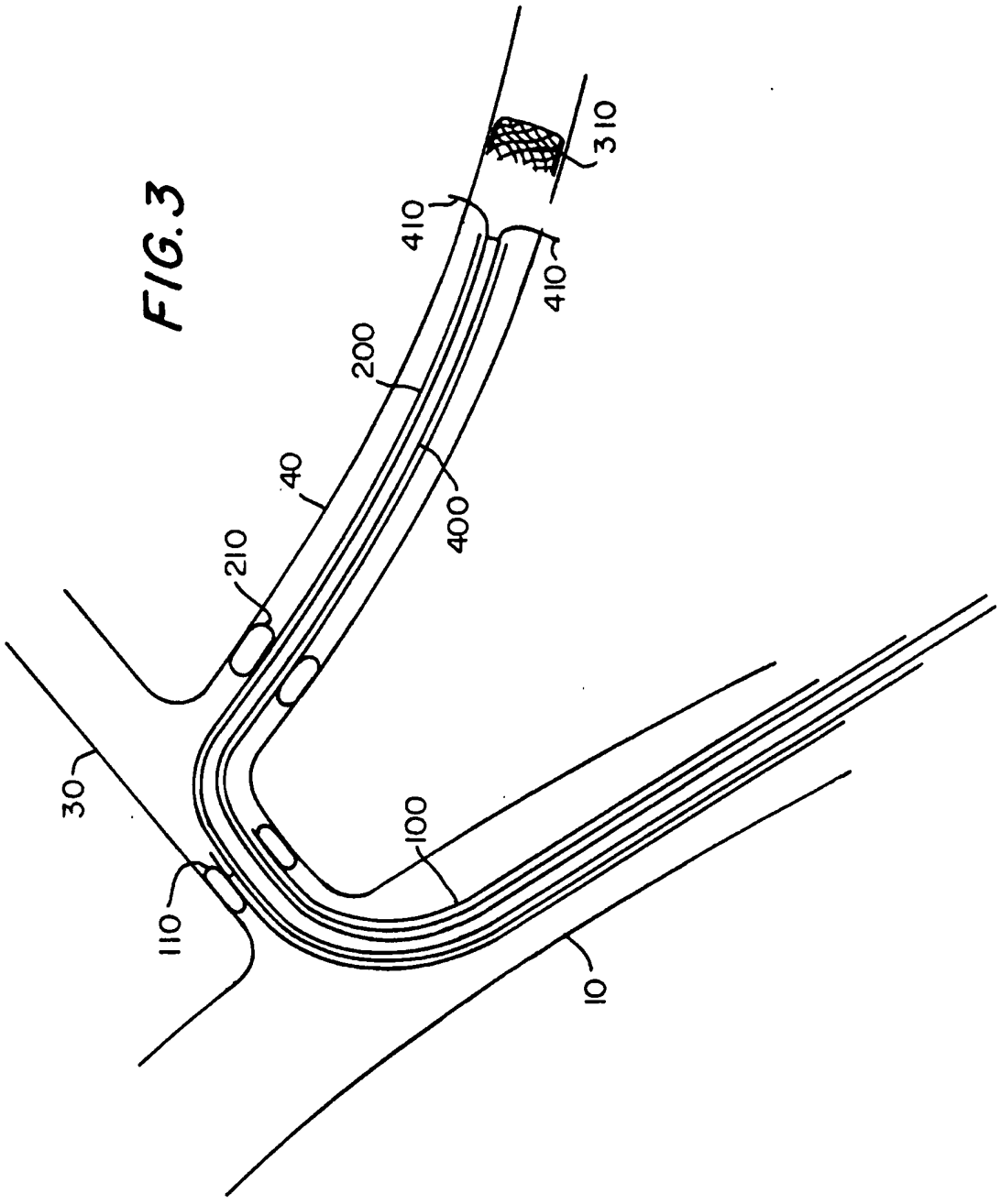
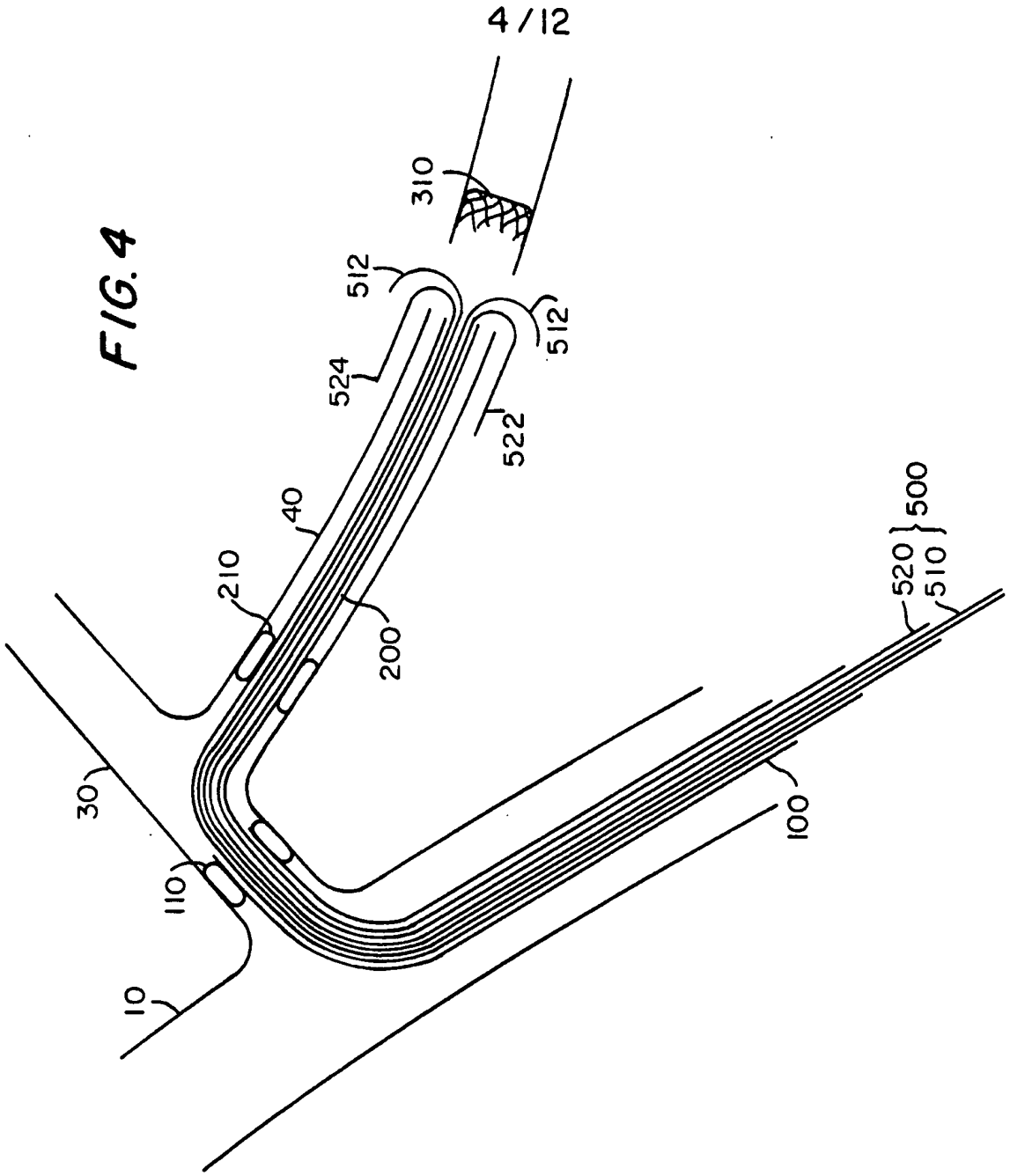


FIG. 4



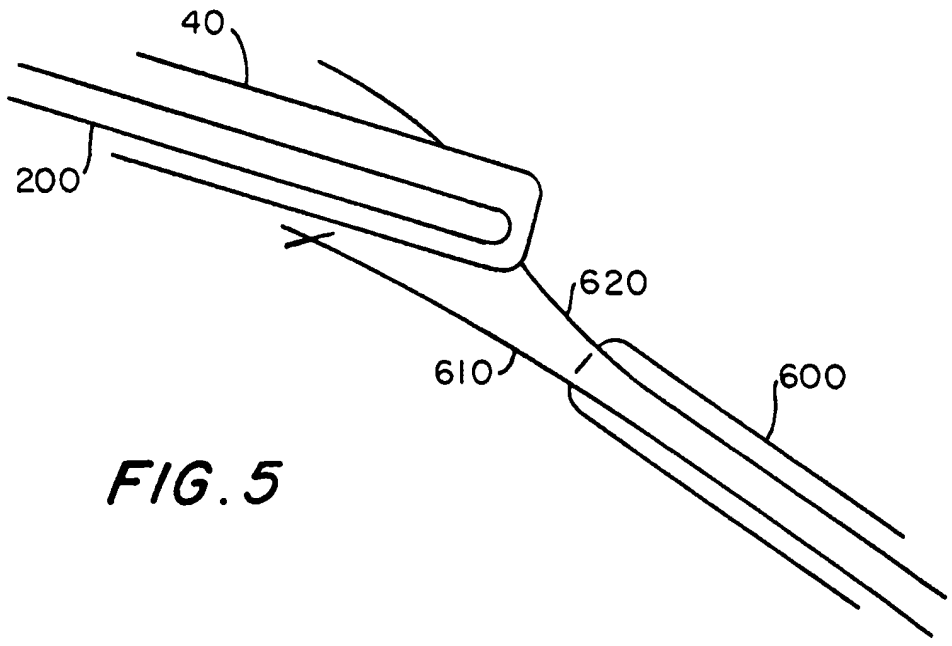
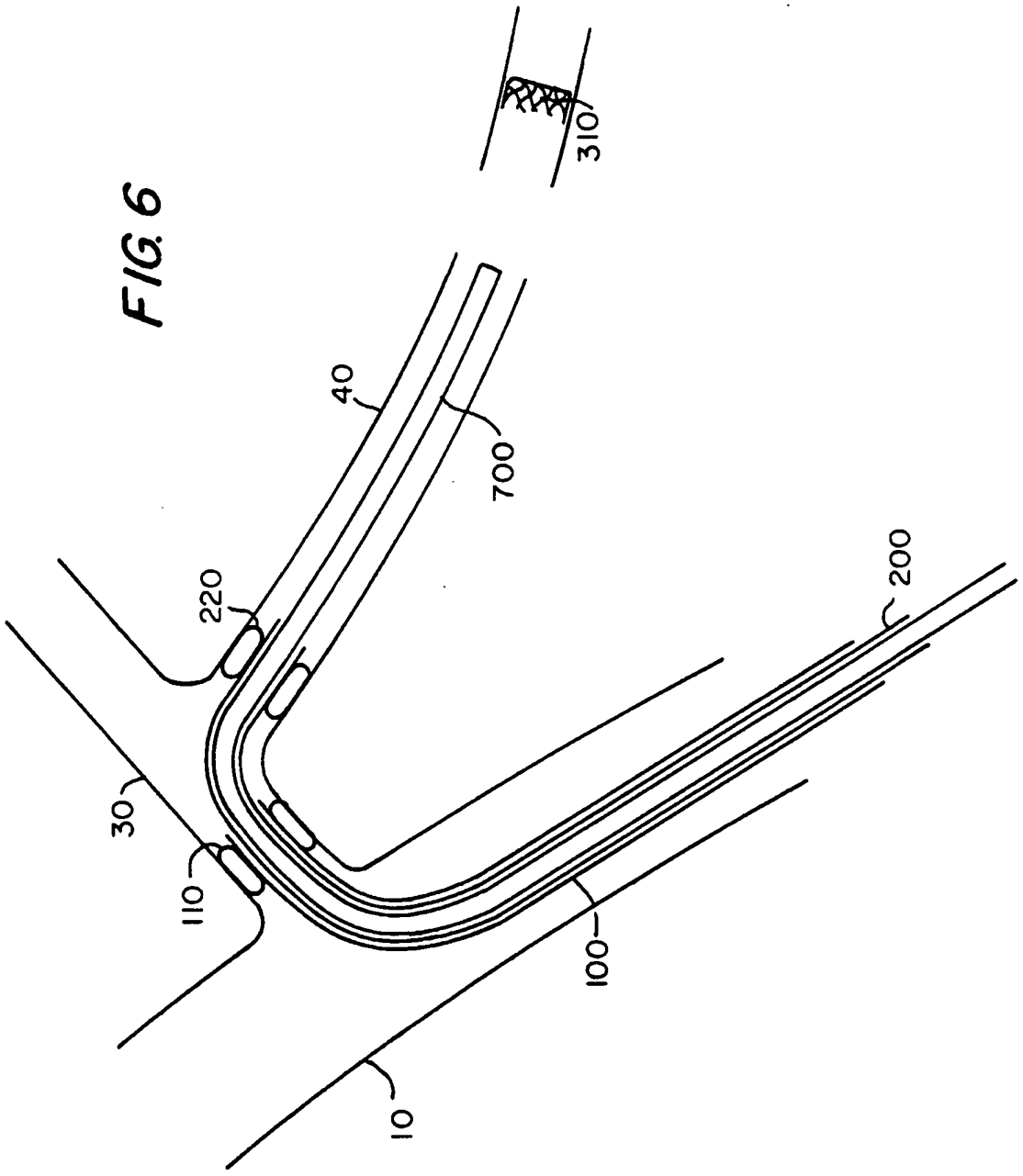
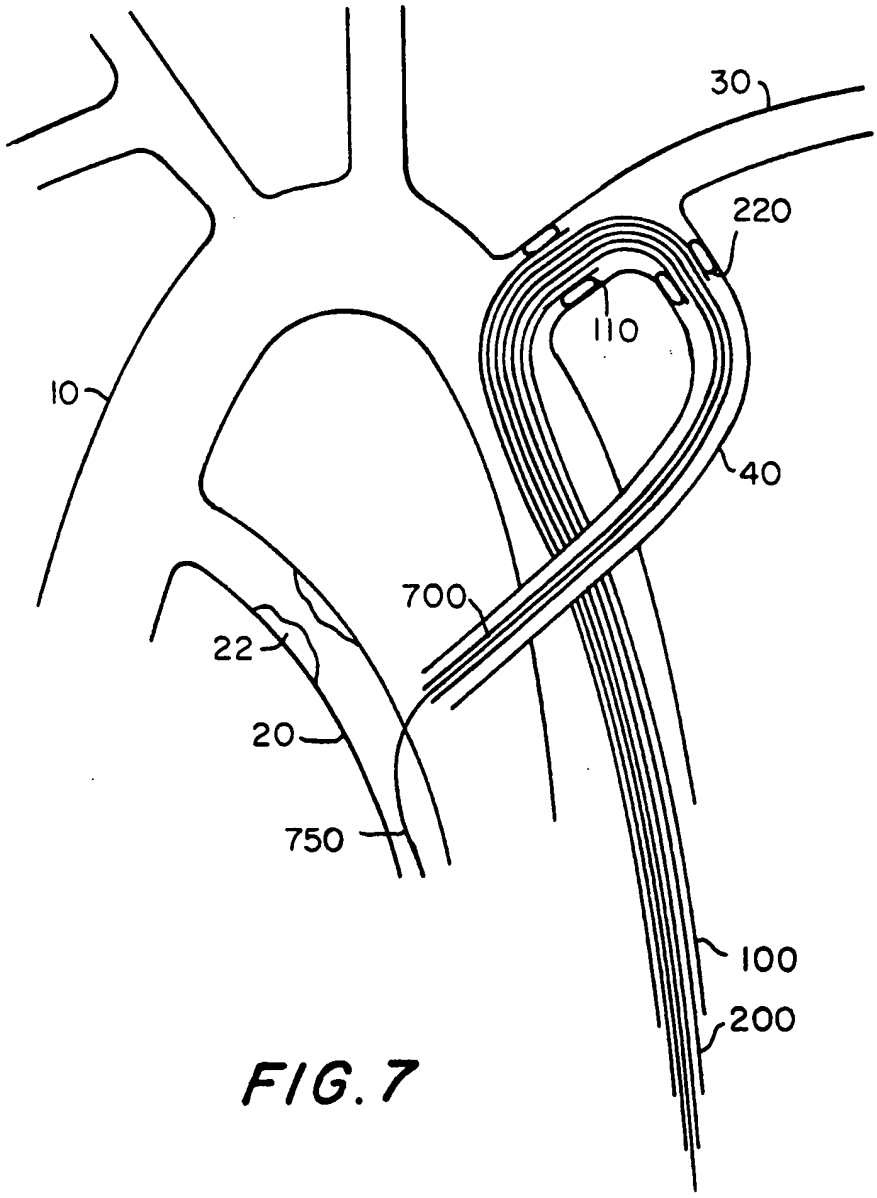


FIG. 5

FIG. 6





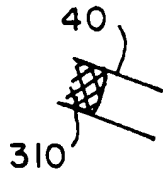


FIG. 7

FIG. 8

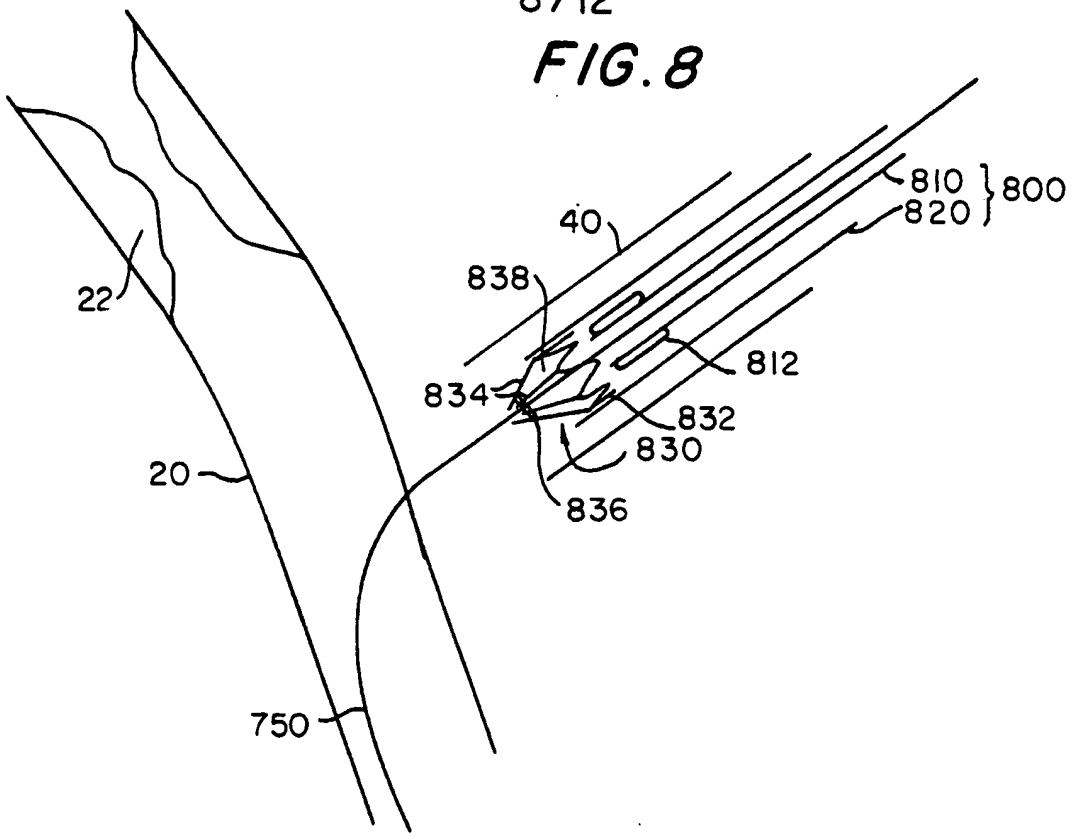

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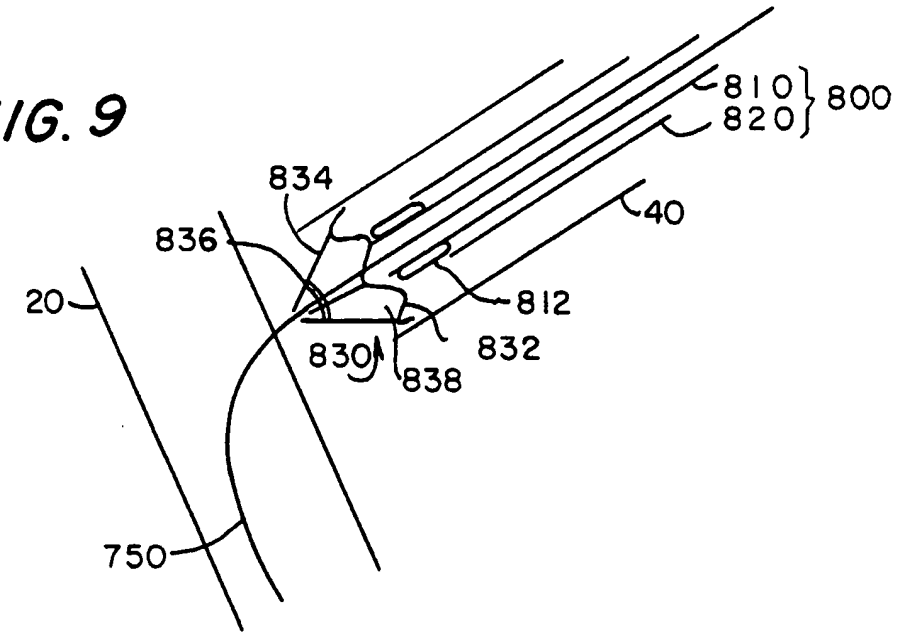
FIG. 9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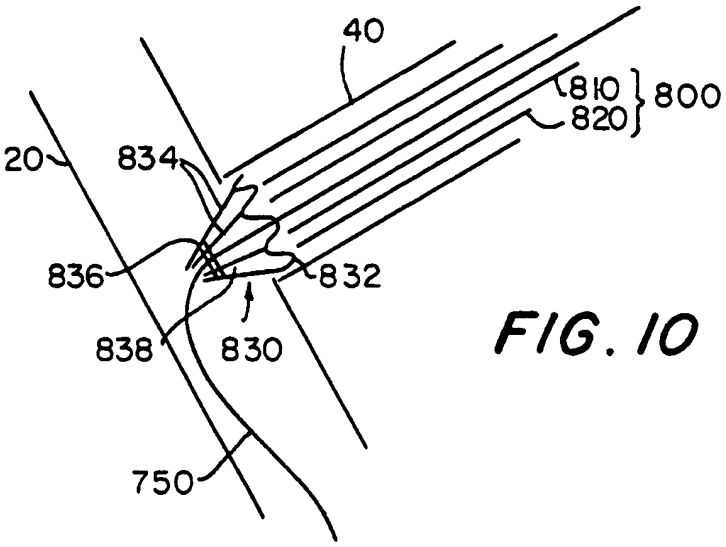
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FIG. 10

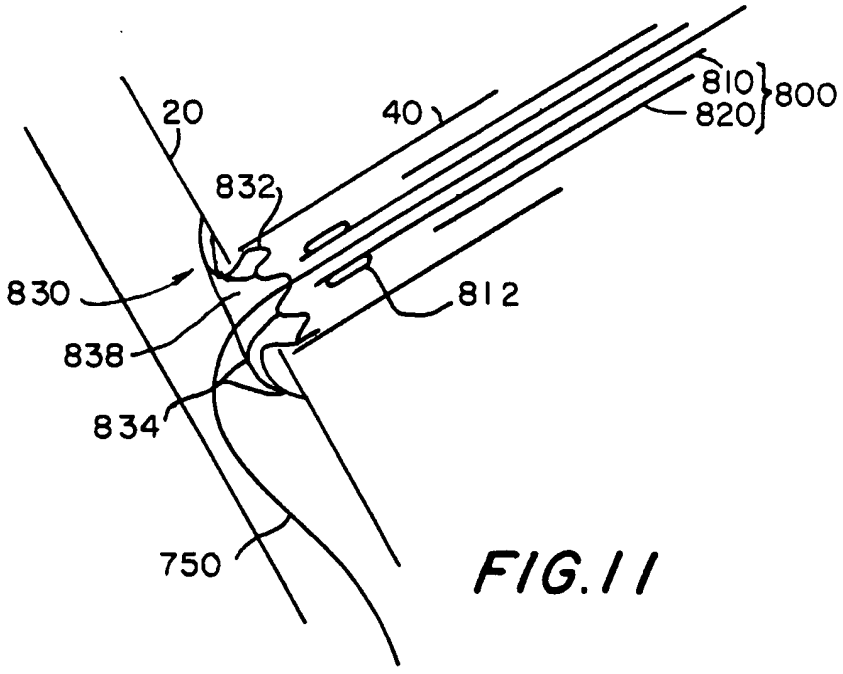
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FIG. 11

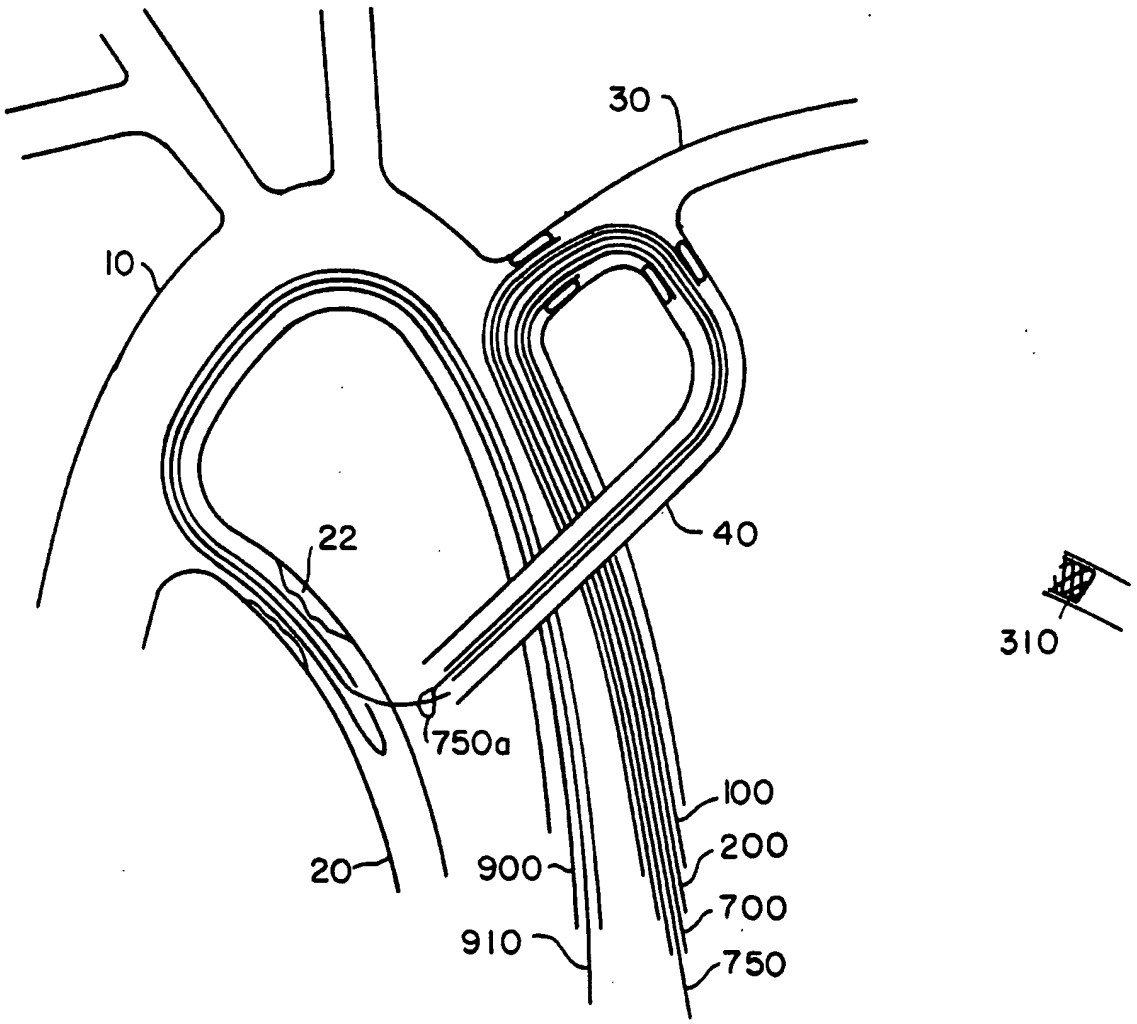

FIG. 12

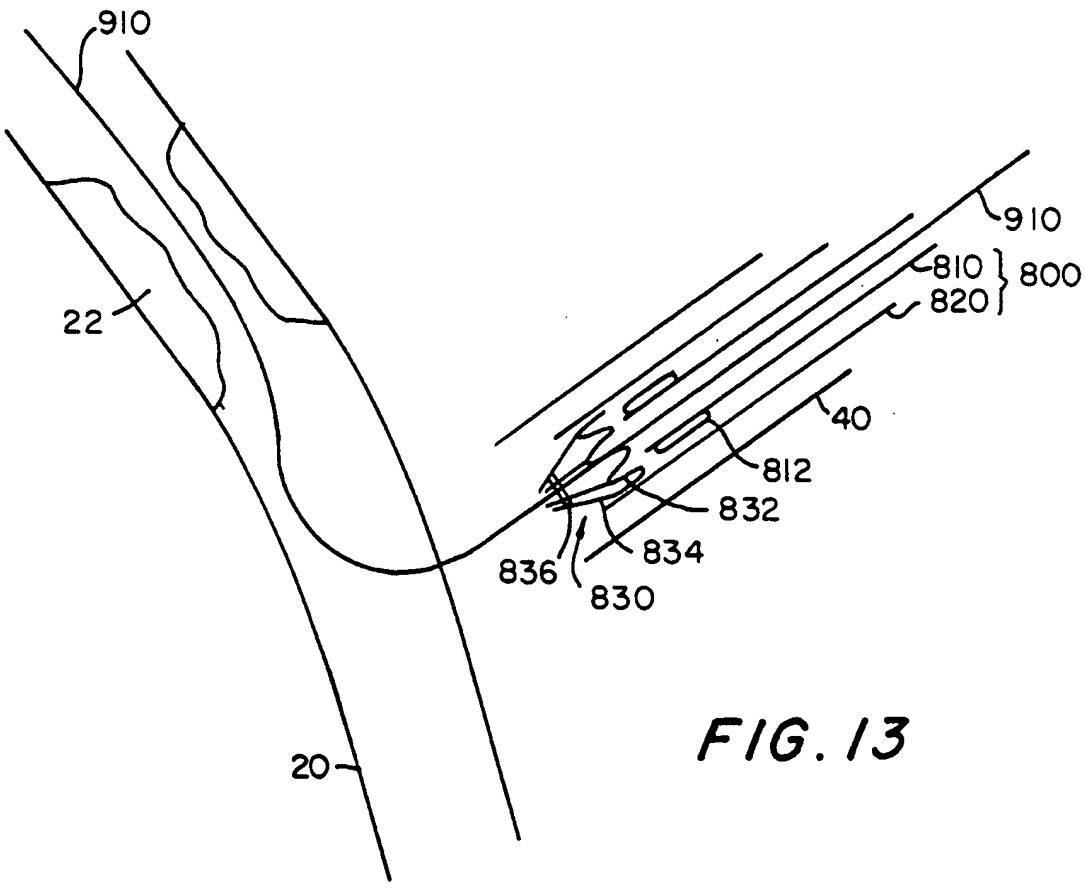

FIG. 13

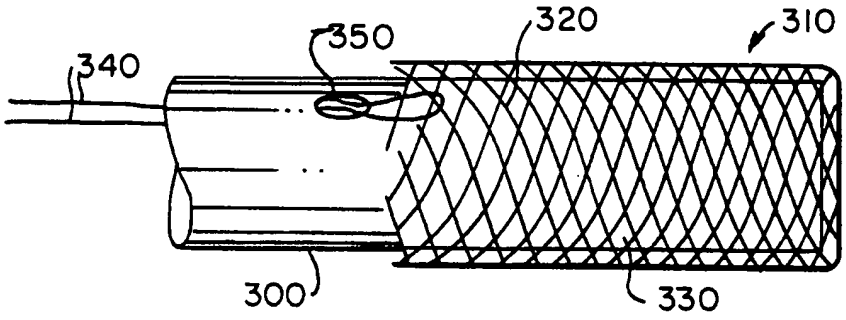

FIG. 14

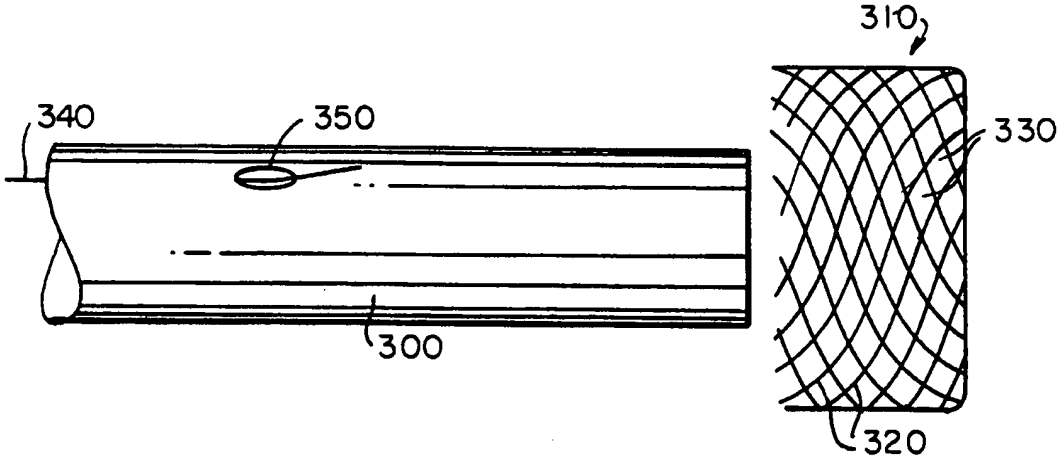

FIG. 15

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(71) Applicant: VASCULAR SCIENCE INC. [US/US]; Suite 202, 701 Decatur Avenue North, Minneapolis, MN 55427 (US).

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(74) Agents: JACKSON, Robert, R. et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).

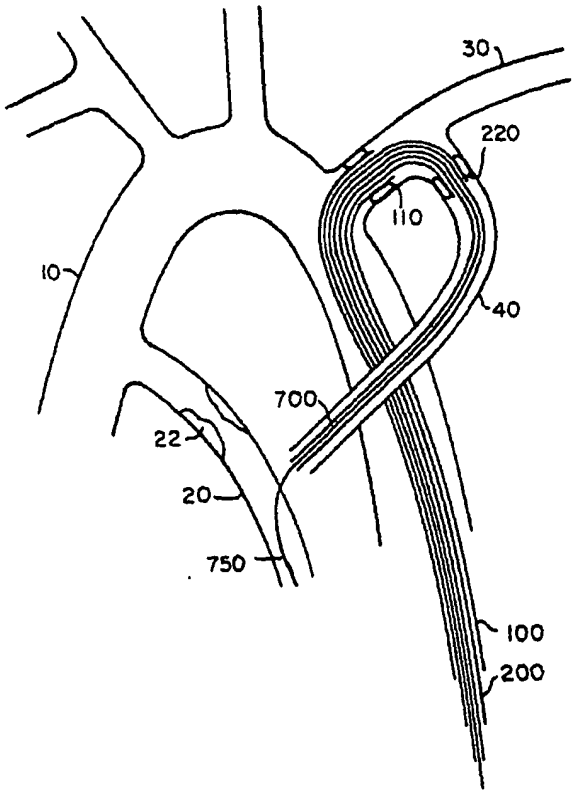
(81) Designated States *(national)*: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

[Continued on next page]

(54) Title: MINIMALLY INVASIVE MEDICAL BYPASS METHODS AND APPARATUS USING PARTIAL RELOCATION OF TUBULAR BODY CONDUIT



(57) Abstract: A tubular body conduit can be partly relocated intralumenally (e.g., to provide a bypass around a narrowing of a tubular body conduit). The tubular body conduit may be plugged intralumenally beyond the part to be relocated. Then the conduit is cut intralumenally. The severed portion of the conduit is relocated intralumenally (e.g., to place the severed end adjacent the side wall of another conduit). The side wall of the other conduit is penetrated intralumenally and the two conduits are connected by a connector that is installed intralumenally.

WO 98/55027 A3

(88) Date of publication of the international search report:
7 June 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 98/09187

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 98 38939 A (SCIMED LIFE SYSTEMS INC) 11 September 1998 see page 6, line 20 - page 13, line 2; figures 1-5	15,24-27
X	US 5 499 995 A (TEIRSTEIN PAUL S) 19 March 1996	15-18, 22,23
A	see column 3, line 6 - line 52; figures 1,2	24-26
X	US 4 710 192 A (LIOTTA DOMINGO S ET AL) 1 December 1987	15-18,23
A	see column 4, line 40 - column 5, line 44; figures 1-3	24-26
X	DE 92 05 797 U (SCHIMITZ-RODE THOMAS ET AL) 17 June 1992	15-17
A	see page 3, paragraph 2; figures 1-3	24-26

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 January 1999	25. 01. 99

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 98/09187

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 527 338 A (PURDY PHILLIP D) 18 June 1996 see column 7, line 32 - column 10, line 33; figures 7-11	15-18,23 24-26
X A	US 5 192 301 A (KAMIYA TETSURO ET AL) 9 March 1993 see column 8, line 35 - line 59; figures 1-9,28,29	15 24-26
A	WO 94 12136 A (BOSTON SCIENT CORP) 9 June 1994 see abstract; figure 1	15,22-26
A	EP 0 249 338 A (BARD INC C R) 16 December 1987 see abstract; figure 1	15
A	WO 97 12555 A (CEDARS SINAI MEDICAL CENTER) 10 April 1997 see page 15, line 3 - page 17, line 18 see page 30, line 11 - page 31, line 22; figures 1,2,12-16	24,29-32
A	US 5 522 834 A (FONGER JAMES D ET AL) 4 June 1996 see abstract; figure 1	24,33, 34,38,39
A	WO 96 40354 A (HEARTPORT INC) 19 December 1996 see page 20, line 32 - page 22, line 17 see page 24, line 10 - page 27, line 28; figures 10-15,22-26	24
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A	EP 0 453 071 A (EVEREST MEDICAL CORP) 23 October 1991 see page 2, line 13 - line 41; figure 1	24,41

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/09187

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-14
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 15-23

Independent Claim 15:
Apparatus for installing a plug in a lumen of a body conduit comprising:
a longitudinal structure configured for insertion into and along the lumen, the longitudinal structure being adapted to releasably carry a plug structure and to releasably retain the plug structure in a configuration small enough to pass along the lumen with the longitudinal structure, and the longitudinal structure including a plug releasing substructure configured to selectively release the plug structure from the longitudinal structure so that the plug structure can enlarge to plug the lumen.

2. Claims: 24-41

Independent Claim 24:
Apparatus for relocating a patient's tubular body conduit comprising:
a longitudinal structure configured for insertion into and along the lumen of the conduit, the longitudinal structure including:
a first substructure configured to make an annular cut in the conduit;
a second substructure configured to shift the cut end of the conduit to a new location in the patient's body; and
a third substructure configured to connect the cut end of the conduit to the patient's body at the new location.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 98/09187

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int .tional Application No
PCT/US 98/09187

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